

## **Remarks**

### *1. Status of the Application*

Claims 20-32 and 67-71 were currently pending. Claims 22, 31, 69 and 71 were objected to as being dependent on a rejected claim. Claims 20, 21, 23, 25-28, 30, 67, 68 and 70 were rejected under 35 U.S.C §102 and claims 20, 21, 23-30, 32, 67, 68 and 70 were rejected under 35 U.S.C. §103. New claims 81-94 are added by this Amendment.

Applicants thank Examiner Ly for removing the finality of the Office action dated January 12, 2004 and for withdrawing the Species Election Requirement dated February 27, 2003. Applicants also gratefully acknowledge Examiner Ly's withdrawal of the prior claim rejections based on the Goodacre et al. and Sockalingum et al. references.

### *2. Summary of Examiner's Interview*

On July 21, 2004, attorney for applicant and Examiners Ly and Marschel discussed the rejection of independent claim 20 based upon the Acheson et al. reference (Acheson et al., *Infection and Immunity*, 61: 1098-1104, 1993). The Examiners explained their interpretation of each of the limitations of claim 20 and why they allege that each is taught by the cited reference. Although no agreement was reached regarding the allowability of claim 20, applicants do greatly appreciate the time taken by the Examiners to clarify the basis of the rejection.

### *3. Support for claim amendments.*

Support for the amendments to claim 20 is found in original claim 22, which has now been canceled. Additional support for these amendments may be found throughout the application, for example, at page 10, lines 4-23, and in Examples 1-7 and 9.

Claim 69 has been amended to depend from claim 20, rather than from claim 22, which has been canceled.

Support for new claims 81, 82, 83 and 84 is provided by independent claim 20 and claims 22, 31, 69 and 71, which have been rewritten in independent form including all of the limitation of base claim 20 and any intervening claims, of which there were none.

Support for new claim 85 can be found throughout the application, for example, at page 1, lines 15-20, where the application states that "[c]hemotaxonomy of microorganisms based upon their spectroscopic, spectrometric and chromatographic characteristics represents a useful

method for the identification of microorganisms,” and that “such chemotaxonomic methods are based upon instrumental methods that provide ‘fingerprint’ spectra.” Additional support can be found in particular at page 6, lines 22-23, from page 16, line 27 to page 17, line 25, and in FIG. 1, and Example 2.

Support for new claims 86 and 88 can be found throughout the application, for example, in FIG. 1 and the associated text found in Example 2 from page 29 to page 32, where fingerprint spectra comprising multiple signals are shown and their transformation according to the disclosed methods are discussed at length. In particular, claim 85 is supported at page 15, lines 23-24, where the application states that “fingerprint spectra of microorganisms reflect the identities and relative concentrations of biomolecules in microorganisms.”

Support for new claim 87 can be found throughout the application, for example, from page 18, line 27, to page 19, line 16, and in Example 1 from page 21 to page 28, which discusses the construction of databases of fingerprint spectra.

Support for new claim 89 can be found, for example, at page 10, lines 11-14.

Support for new claim 90 can be found, for example, at page 10, lines 14-16.

Support for new claim 91 can be found, for example, at page 10, lines 17-18.

Support for new claim 92 can be found, in Example 5 at pages 48-52.

Support for new claim 93 can be found, for example, at page 10, lines 18-19.

Support for new claim 94 can be found, for example, at page 10 lines 19-21, and at page 12, line 20.

#### *4. Objections*

Claims 22, 31, 69 and 71 were objected to for being dependent on a rejected base claim, but otherwise allowable if rewritten in independent form including all of the limitation of the base claim and any intervening claims. New claims 81, 82, 83 and 84 are added by this amendment and represent claims 22, 31, 69 and 71, respectively, but rewritten in independent form, including all of the limitations of the base claim and any intervening claims. Claims 81-84 should be allowed.

5. *Rejections under 35 U.S.C. §102*

Claims 20, 21, 23, 25-28, 30, 67, 68 and 70 were rejected as allegedly being anticipated by Acheson et al. (Acheson et al., *Infection and Immunity*, **61**: 1098-1104, 1993). Applicants traverse these rejections for the reasons outlined below.

Claim 20 has been amended to recite the feature “wherein the fingerprint spectra are selected from the group consisting of mass spectra, infrared spectra, ion-mobility spectra, gas chromatograms, liquid chromatograms, and nuclear magnetic resonance spectra, and portions and combinations thereof.” Acheson et al. does not teach or suggest any of these types of fingerprint spectra, and therefore, does not anticipate claim 20. Furthermore, amended claim 20 recites the broad types of fingerprint spectra that were formerly recited in claim 22, which was indicated to be allowable in the Office action. Applicants respectfully request allowance of amended claim 20.

The amendments to claim 20 have been made solely to expedite issuance of a Notice of Allowance. Applicants submit, for example, that the term “fingerprint spectra” was interpreted more broadly than reasonable in support of the rejections set forth in the Office action. Therefore, applicants reserve the right to prosecute claim 20 without the present amendments in a continuing application.

Claims 21, 23, 25-28, 30, 67, 68 and 70 are not anticipated for at least the reasons given above for claim 20, from which they all depend. Furthermore, claims 21, 23, 25-28, 30, 67, 68 and 70 recite patentably distinct combinations of features that are not taught or suggested by the Acheson et al. reference. Claims 21, 23, 25-28, 30, 67, 68 and 70 should be allowed.

6. *Rejections under 35 U.S.C. §103*

Claims 20, 21, 23-30, 32, 67, 68 and 70 were rejected as allegedly being obvious in view of Acheson et al. (Acheson et al., *Infection and Immunity*, **61**: 1098-1104, 1993) taken together with Jeng et al. (US Patent No. 6,087,182). Applicants traverse these rejections for the reasons outlined below.

Since the Acheson et al. reference does not teach or suggest the features of claim 20, from which claims 21, 23-30, 32, 67, 68 and 70 depend, a combination of the Acheson et al. reference with Jeng et al. does not disclose each and every limitation of these claims, and

therefore, a *prima facie* case of obviousness is not established by the Office action. Claims 20, 21, 23-30, 32, 67, 68 and 70 should be allowed.

7. *Patentability of New Claims 85-94.*

New claim 85 is patentable because it is not anticipated by, nor is it obvious in view of, the Acheson et al. reference. Acheson et al. does not teach or suggest any fingerprint spectra, nor does it teach or suggest any method for correcting for drift in such fingerprint spectra, let alone any method including the recited features of claim 84. Claim 84 also includes the clarifying feature that the fingerprint spectra to which the method can be applied are spectroscopic, spectrometric and chromatographic fingerprint spectra.

One of ordinary skill in the art would recognize that the data provide in Figures 3 and 4, and the data of Tables 1 and 2, of the Acheson et al are not spectra (let alone fingerprint spectra as alleged in the Office action). Furthermore, the allegation that the data appearing in these tables and figures are fingerprint spectra is contrary to the ordinary meaning of the word “spectra” alone, and certainly contrary to the term in combination with the terms “spectroscopic,” “spectrometric,” and “chromatographic.” The Federal Circuit has repeatedly emphasized that there is a “‘heavy presumption’ that a claim term carries its ordinary and customary meaning.” *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). Furthermore, “[t]he terms used in claims bear a ‘heavy presumption’ that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art.” *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002).

Enclosed are definitions from the Merriam-Webster Online Dictionary of the following terms: spectrum (*plural* spectra), spectroscope (*adjective* spectroscopic), spectrometer (*adjective* spectrometric), chromatogram and chromatography (*adjective* chromatographic). Taken together, these definitions demonstrate how the allegation in the Office action that the Acheson et al. reference teaches “finger print spectra” is contrary to the ordinary meaning of this term, and certainly contrary to the meaning that would be attributed to the term by one of ordinary skill in the art, especially as modified by the clarifying adjectives “spectroscopic,” “spectrometric” and “chromatographic.”

As seen in the enclosures, a “spectrum” is defined “a continuum of color formed when a beam of white light is dispersed (such as by passage through a prism) so that its component wavelengths are arranged in order,” “any of various continua that resemble a spectrum in consisting of an ordered arrangement by a particular characteristic (as frequency or energy),” or “a representation (as a plot) of a spectrum.” The term “spectroscopic” pertains to something generated by “an instrument for forming and examining spectra.” The term “spectrometric” pertains to “an instrument used for measuring wavelengths” or “any of various analytical instruments in which an emission (as of particles or radiation) is dispersed according to some property (as mass or energy).” Clearly, the ordinary meaning of spectra refers to a plurality of wavelengths or masses that are dispersed. No such dispersion, for example, of multiple wavelengths or masses, appears in Acheson et al., and no method for correcting for drift in such dispersions is taught or suggested by Acheson et al.

The adjective “chromatographic” which is subsumed within the term “fingerprint spectra” in claim 85 pertains to “a process in which a chemical mixture carried by a liquid or gas is separated into components as a result of differential distribution of the solutes as they flow around or over a stationary liquid or solid phase.” The result of a chromatographic separation is a chromatogram, which is “the pattern formed on the adsorbent medium by the layers of components separated by chromatography,” or “a time-based graphic record (as of concentration of eluted materials) of a chromatographic separation.” Clearly, the ordinary meaning of a “chromatogram,” or “chromatographic spectra” refers to a representation of multiple components obtained from a chromatographic separation, either as a pattern or a time-base record. No such patterns of multiple components or time-based records of chromatographic separations appear in Acheson et al., and no method for correcting for environmental drift in such patterns or records is taught or suggested by Acheson et al.

In contrast to the definitions discussed above, the Acheson et al. reference teaches only a measurement of the amount of light absorbed at a single wavelength (the optical density, OD, at 600 nm), not a dispersion of wavelengths that would be consistent with the ordinary meanings of “spectroscopic,” “spectrometric,” and “spectra,” or consistent with the meanings that would be attributed to these terms by one of ordinary skill in the art. Acheson et al. also does not teach or suggest any “chromatographic spectra,” rather it teaches the concentrations of a single component, namely the SLT-I B subunit. Although Acheson et al. teaches the concentration of

the subunit over time in Figures 3C and 4C, these graphs are not time-based graphic records of chromatographic separations. In other words, Acheson et al. does not disclose any data that could be considered “chromatographic fingerprint spectra,” and does not teach or suggest any method for correcting for drift in such spectra.

Therefore, since Acheson et al. does not disclose “spectroscopic, spectrometric and chromatographic spectra,” and does not teach or suggest any method for correcting for drift in such spectra, it cannot anticipate claim 84. Furthermore, when the phrase “spectroscopic, spectrometric and chromatographic fingerprint spectra,” is given a meaning that is reasonable in view of the clear meaning of the term, Acheson et al. does not teach or suggest additional features appearing in claim 85.

New claims 86-88 are patentable for at least the reasons given for claim 85 from which they depend. In addition, claim 86 includes the feature of “wherein the fingerprint spectra comprise multiple signals that reflect the identities and relative concentrations of biomolecules in the microorganisms,” a feature which is not taught or suggested by the Acheson et al. reference. Claim 88 adds the language of “wherein the multiple signals in each spectrum are transformed into multiple signals in each transformed spectrum.” This feature also is not taught or suggested by Acheson et al..

Claim 87 is patentable for at least the reasons given for claim 85 from which it depends. In addition, claim 87 adds the feature of “wherein the multiple signals of the fingerprint spectra are stored in a database.” Acheson et al. does not teach or suggest a database.

Claims 89-94 are patentable for at least for the reasons given for claim 20 from which they depend, and because they recite particular types of fingerprint spectra that are not taught or suggested by the Acheson et al. reference. Some of the specific types of spectra recited in these new claims were in formerly in claim 22, which was indicated to be allowable in the Office action.

*IV. Conclusion*

All claims are in condition for allowance. However, if any issues remain before a Notice of Allowance is issued, Examiner Ly is invited to telephone the undersigned patent attorney at the number provided below.

Respectfully submitted,

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